(19) FEDERAL REPUBLIC OF GERMANY GERMAN PATENT OFFICE

(51) Int. Cl.⁶: **A61M 29/00** A 61 F 2/08 A 61 L 27/00

(12) Utility Patent (10) DE 297 01 758 U1

(21) Serial number:

297 01 758.6

(22) Date of application:

February 1, 1997

(47) Date recorded:

March 27, 1997

(43) Publication in the Patent Gazette:

May 7, 1997

(73) Owner:

Jomed Implantate GmbH, 72414 Rangendingen, Germany

(74) Attorneys:

Möbus und Kollegen, 72762 Reutlingen

Search request according to § 7, Par. 1, Utility Patent Act, has been submitted.

(54) Radially expandable stent for implantation in a blood vessel, especially in the vicinity of a vascular bifurcation

Jomed Implantate GmbH Rudolf-Diesel-Strasse 29 72414 Rangendingen

Radially expandable stent for implantation in a blood vessel, especially in the vicinity of a vascular bifurcation

In cardiology, stents are introduced into vessels to prevent reocclusions of the vessels, especially after vascular dilation procedures. Vascular blockages can also occur in the vicinity of vascular bifurcations. After expanding the vessel with a balloon catheter, it may be necessary to secure the entire bifurcation area with stents. In the past, ordinary stents (coil stents, multicellular stents, or the like) with relatively small, evenly distributed openings or interstices have been used for that purpose; in the process, a first stent is advanced with a balloon catheter until it crosses the bifurcation area and expanded. Then a second stent, in its unexpanded state, is introduced into the side branch vessel through one of the openings or interstices of the first stent, and then likewise expanded. Often, though, it is quite difficult to pass the second stent through one of the radial openings, usually rather narrow, in the first stent. Also, only limited expansion of the second stent is possible in the area of its passage through the first stent. Thus the two stents exert a high resistance to flow in the transitional area of the two vessels. Therefore, bifurcations are particularly susceptible to renewed vascular blockage or to causing thromboses. Even if just one stent is used in the main vessel, there is a high resistance to flow in the bifurcation area because of the small openings or interstices of known stents.

As a remedy for this problem, the invention proposes a radially expandable stent for implantation in a blood vessel, especially in the vicinity of a vascular branch, in the form of a hollow cylindrical element characterized in that it has, in its expanded state, at least one section with enlarged radial openings. If such a stent is advanced such that its section with enlarged radial openings lies across the bifurcation site of the second vessel, then it is easy to pass the second stent through one of the enlarged openings into the second vessel. In addition, blood flow into the side branch vessel is not hindered at the intersection of both stents if they are correctly positioned. The segment, of which there

may be more than one, with enlarged radial openings can conveniently be in the form of a hollow cylinder. This simplifies insertion of the stent into the vessel, as it is not necessary to ensure a particular orientation of the radial openings. It is convenient for the diameters of the enlarged radial openings to be such that a second unexpanded stent can easily be passed through the openings. For example, the enlarged radial openings can be in the form of a rhomboid or other polygon, a circle or an ellipse. A stent with such openings can be made, preferably, by laser cutting from a seamless metal tube. The stent can also have multiple sections with enlarged radial openings. The stent can preferably be made so that its radial stiffness in the section, of which there may be more than one, with enlarged radial openings is at least approximately equal to the radial stiffness in the other sections. In one preferred embodiment, one half of the stent can have enlarged radial openings. In the case of a vascular bifurcation, both stents inserted there can conveniently have this form. After insertion, the areas of enlarged radial openings on the two stents are superimposed, so that approximately the same coverage factor of the vascular wall can be attained in the area of superimposition as is obtained in the other vascular areas in which the halves of the stents with normal-size radial openings individually stiffen the vessel. To be able to monitor the position of a stent in the vessel during insertion, it is advantageous for the stent to be made of a material which is easily visible in X-ray fluoroscopy, or to have a coating of such material, at least in the area of the enlarged radial openings. For that purpose, for example, the appropriate area of the stent can be made of platinum or gold, or can have a platinum or gold coating.

A preferred embodiment of a stent according to the invention is described in more detail below, using the drawing.

Figure 1 shows a schematic view of a vascular bifurcation with inserted stents;

Figure 2 shows a representation of the surface structure of a stent according to the invention in the expanded state;

Figure 3 shows the surface structure of the stent described in Figure 2 in its unexpanded state.

Figure 1, in a drawing indicating the principle, shows a first blood vessel 10 from which a second blood vessel 11 branches. A first stent 12 is inserted into the first blood vessel and extends past the area where vessel 11 branches off. Another stent 13 is introduced into the inside of stent 12, with one of its ends extending into the second blood vessel 11. To facilitate the introduction of the inner, second stent 13 into the second blood vessel 11, the first stent 12 has a hollow cylindrical area 14 with enlarged radial openings, indicated by dashed lines, through which the second stent 13 can be passed in its unexpanded state.

Figure 2 shows the surface structure of such a stent with enlarged radial openings 15 which, in the example presented, have a hexagonal shape with a diameter that is several times larger than the diameter of the other radial openings 16. Figure 2 also shows the cross-section of a second stent 17, which in its radially unexpanded state can be passed relatively easily through the enlarged openings 15.

Figure 3 shows the surface structure of the stent according to Figure 2 in its radially unexpanded state.

The stent shown is only an example. Instead of just one area with enlarged radial openings, there can also be many such areas. It is also possible to make one half of the stent with radially enlarged openings and the other half with radial openings of normal size.

Claims:

- 1. Radially expandable stent for implanting in a blood vessel, especially in the area of a vascular bifurcation, in the form of a hollow cylindrical element, characterized in that it has at least one section (14) in its expanded state.
- 2. Stent according to Claim 1, characterized in that the section (14), of which there may be more than one, with enlarged radial openings (15) is a hollow cylinder.
- 3. Stent according to Claim 1 or 2, characterized in that the diameter of the enlarged radial openings (15) is made so that a second unexpanded stent (13, 17) can easily be passed through the openings.
- 4. Stent according to one of Claims 1 to 3, characterized in that the enlarged radial openings (15) have the shape of a rhombus or other polygon.
- 5. Stent as described in one of Claims 1 to 3, characterized in that the enlarged radial openings (15) have the shape of a circle or an ellipse.
- 6. Stent according to one of Claims 1 to 5, characterized in that its radial stiffness in the section (14), of which there may be more than one, with enlarged radial openings (15) is at least approximately equal to the radial stiffness in the other sections.
- 7. Stent according to one of Claims 1 to 6, characterized in that it has multiple sections (14) with enlarged radial openings (15).
- 8. Stent according to one of Claims 1 to 6, characterized in that one of its halves has enlarged radial openings (15).

- 9. Stent according to one of Claims 1 to 8, characterized in that it is made substantially of a material that is well visible in X-ray fluoroscopy, or has a coating of such a material, at least in the vicinity (14) of the enlarged radial openings (15).
- 10. Stent according to Claim 9, characterized in that that it is made of platinum, or has a platinum coating, at least in the vicinity (14) of the enlarged radial openings (15).
- 11. Stent according to Claim 9, characterized in that it is made of gold, or has a gold coating, at least in the area (14) of the enlarged radial openings (15).

DM/H